Hazard Analysis and Critical Control Points (HACCP) and Their Relationship to the Quality System Regulation

Seven Principles of HACCP

1. Conduct hazard analysis and identify preventive measures.
2. Identify critical control points.
3. Establish critical limits.
4. Monitor each critical control point.
5. Establish corrective action to be taken when deviation occurs.
6. Establish record-keeping system.
7. Establish verification procedures.

What is the relationship between the seven principles of HACCP and the QS Regulation?

1. Conduct hazard analysis and identify preventive measures.

- 820.30(g) - Design validation shall include . . . ***risk analysis***, where appropriate.
- 820.70(a) - Where deviations from device specification could occur as a result of the manufacturing process, the manufacturer shall establish and maintain process control procedures that describe ***any process controls necessary to ensure conformance to specifications.***

1. Conduct hazard analysis and identify preventive measures. (cont.)

- Examples of preventive measures:
  - 820.50 - Purchasing controls
  - 820.86 - Receiving, in-process, and finished device acceptance
  - 820.70(c) - Environmental controls
  - 820.70(d) - Personnel
  - 820.70(e) - Contamination control
  - 820.70(g) - Equipment maintenance
  - 820.72 - Inspection, measuring and test equipment

2. Identify critical control points.

- 820.30(g) - Design validation shall include . . . ***risk analysis***, where appropriate.
- 820.70(a) - Where deviations from device specification could occur as a result of the manufacturing process, the manufacturer shall establish and maintain process ***control*** procedures that describe any ***process controls necessary to ensure conformance to specifications.***

3. Establish critical limits.

- 820.70(a) - Each manufacturer shall ***develop,*** conduct, control, and monitor ***production processes*** to ensure that a device conforms to its specifications.
- 820.70(a) - Where process controls are needed they shall include: (2) Monitoring and control of ***process parameters*** and ***component and device characteristics*** during production.

4. Monitor each critical control point.

- 820.70(a) - Where process controls are needed they shall include: (2) ***Monitoring*** and control ***of process parameters and component and device characteristics*** during production.

5. Establish corrective action to be taken when a critical limit deviation occurs.

- 820.100(a) - Each manufacturer shall establish and maintain procedures for implementing corrective and preventive action. The procedures shall include requirements for: (3) ***Identifying the actions(s) needed to correct and prevent recurrence of nonconforming product and other quality problems.***

6. Establish a record-keeping system.

- 820.70(a) - Where process controls are needed they shall include: (1) ***Documented instructions, standard operating procedures (SOPs) and methods*** that define and control the manner of production;
- 820.100(b) - ***All activities required under this section, and their results, shall be documented.***
- 820.181 - Device master record
- 820.184 - Device history record
- 820.186 - Quality system record

7. Establish verification procedures.

- 820.80 - Each manufacturer shall establish and maintain procedures for acceptance activities. Acceptance activities include inspections, tests, or other ***verification activities.***
- 820.100(a) - Each manufacturer shall establish and maintain procedures for implementing corrective and preventive action. The procedures shall include requirements for: (4) ***Verifying or validating the corrective and preventive action to ensure that such action is effective and does not adversely affect the finished device***;